

frame 3' of nucleic acids coding for a signal peptide; and

(b) a control region linked operably with the coding region, said control region comprising a plurality of promoters and at least one ribosome binding site, wherein at least one of said promoters is tac, and

wherein recovering said peptide product comprises:

(a) separating host cells from the culture medium; [and]

(b) subjecting the medium to cation exchange chromatography and recovering fractions containing said peptide product; and

(c) subjecting the recovered fraction of step (b) to reverse-phase liquid chromatography and recovering fractions containing peptide product;

(d) subjecting the recovered fractions of step (c) to cation exchange chromatography[,]; and

(e) thereafter recovering fractions containing peptide product.--

#### REMARKS

Claims 1-101 were pending in this application. According to the August 13, 1999 Office Action, claims 3, 4, 16-19, 21, 28-31, 39, 44-64, 68-69, 71-72 and 74-101 were withdrawn from consideration; claims 32-36 were allowed; claims 1, 5-14, 20, 22-24, 27, 37, 41-43 and 65-67 were rejected; and claims 2, 15, 25, 26, 38, 40, 70 and 73 were objected to. Applicants have canceled claims 2-4, 16-19, 21, 28-31, 39, 44-66, 68-69, 71-72 and 74-101 without prejudice and amended claims 15, 25, 26, 38, 40, 43, 67, 70, and 73. Thus, claims 1, 5-15, 20, 22-27, 32-38, 40-43, 67, 70, and 73 are now under consideration.

#### Election

Applicants have hereinabove canceled claims 3, 4, 16-19, 21, 28-31, 39, 44-64, 68-69, 71-72 and 74-101 without prejudice since they are drawn to a non-elected invention.

#### Duplicate Claims

The Examiner advised applicants that should claims 41 and 42 be found allowable, claims 65 and 66 will be objected to under 37 C.F.R. §1.75 as being a substantial duplicate thereof. In response, applicants have hereinabove canceled claims 65 and 66.

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**Allowable Subject Matter**

Applicants note with appreciation the Examiner's indication that claims 32-36 are allowable and the claims 2, 15, 25, 26, 38, 40, 70 and 73 are objected as being dependent upon a rejection of a base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. In response, applicants have hereinabove amended claims 15, 25, 26, 38, 40, 70 and 73 as independent claims including all of the limitations of the base claim and any intervening claims as the Examiner suggested.

**Rejection under 35 U.S.C. §112, second paragraph**

The Examiner rejected claims 43 and 67 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

In response, applicants have hereinabove amended claims 43 and 67 to add a coma between the second and third alternatives of the Markush group as the Examiner requested.

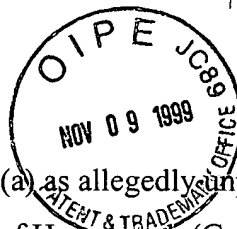
**Rejection under 35 U.S.C. §102(b)**

The Examiner rejected claims 1, 6, 7, 9, 20, 22-24 and 37 under 35 U.S.C. §102(b) as allegedly anticipated by Koke et al. (Prot. Exp. & Purification (1991) 2:51-58).

In response, applicants have hereinabove amended claim 1 to include the limitations of claim 2 which is allowed. Since claims 6, 7, 9, 20, 22-24 and 37 are dependent on amended claim 1, they should be allowed as well. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

**Rejection under 35 U.S.C. §103(a)**

The Examiner rejected claims 1, 6, 7, 9, 11-13, 20, 22-24, 27, 37, 41 and 65 under 35 U.S.C. §103(a) as allegedly unpatentable over Koke et al. further in view of Ray et al. (Biotechnology (Jan. 1993) 11:64-70). The Examiner also rejected claims 1, 6, 7, 9, 11, 12, 14, 20, 22-24, 37, 42 and 66 under 35 U.S.C. §103(a) as allegedly unpatentable over Koke et al. and further in view of Craig et al. (U.S. Patent No. 5,332,664). The Examiner also rejected claims 1,



5-9, 10, 20, 22-24, 37 and 38 under 35 U.S.C. §103(a) as allegedly unpatentable over Inouye et al. (U.S. Patent No. 4,757,013) and further in view of Hasan et al. (Gene (1987) 56:145-151).

In response, applicants have hereinabove amended claim 1 to include the limitations of claim 2 which is allowed. Since claims 5-14, 20, 22-24, 27, 37, 41, 42, 65 and 66 are dependent on amended claim 1, they should be allowed as well. Claim 38 has been deemed allowable by the Examiner but has been rejected under this section apparently by mistake. The Examiner is kindly requested to take note of that. Accordingly, respectfully applicants that the Examiner withdraw this rejection.

In light of the foregoing amendments and remarks, it is respectfully submitted that this application is now in condition to be allowed and the early issuance of a Notice of Allowance is respectfully solicited. If there are any issues or amendments the Examiner wishes to discuss, the Examiner is encouraged to contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on November 5, 1999:  
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November 5, 1999  
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Date of Signature

WOG/CCA:lac

Respectfully submitted,

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